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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,220	04/06/2004	Jeff McElroy	DEKA:344US	7115

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EXAMINER

BUI, PHUONG T

ART UNIT PAPER NUMBER

1638

DATE MAILED: 09/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/820,220

Applicant(s)

MCELROY, JEFF

Examiner

Phuong T. Bui

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8/23/04</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

1. Claim 1-24 are pending and are examined in the instant application.

Drawings

2. No drawings have been submitted in the instant application.

Specification

3. All citations of US filed applications in the specification should also be updated where appropriate, see for example, page 24.

Claim Rejections - 35 USC § 112, 2nd paragraph

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The ATCC Accession Number must be filled in where appropriate to clearly provide the identifying characteristics for Applicant's corn variety designation. Compliance with this requirement may be held in abeyance until allowability is indicated.

In claim 3, when the claimed part of the plant is a seed, it is interpreted to mean the seed which produces the claimed plant. If Applicant intends to encompass a hybrid seed, then this claim would be included in the 35 USC 112, first paragraph, written description rejection below.

In claim 10, it is suggested that "derived" be amended to "obtained", as it is unclear what is being retained in the derived product.

In claim 11, it is suggested that “capable of expressing” be amended to “having”, as no conditions for expressing are set forth to define “capable of”, and “expressing” implies protein expression, which does not appear to be Applicant’s intention.

In claims 16 and 21, “yield enhancement”, “improved nutritional quality”, “decreased phytate content”, “modified fatty acid metabolism” and “modified carbohydrate metabolism” and “restoration of male sterility” are not traits. Furthermore, they lack a comparative basis.

In claim 18, the “derived” corn plant of (a) is not the same as the “derived” corn plant of (d). It is unclear what is being retained in each of the “derived” product.

In claim 19, the metes and bounds of “both alleles at substantially all of the loci consist essentially of the allele” are unclear: how could two alleles contain one allele? Furthermore, it is unclear whether “consist essentially of” in claims 19 and 23 means the number of alleles at the same locus may vary or that the allele itself can have structurally differences.

Clarification and/or correction are required.

Claim Rejections - 35 USC § 112, 1st paragraph, deposit

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to

make and/or use the invention. Since the seed claimed is essential to the claimed invention, it must be obtainable by a reproducible method set forth in the specification or otherwise be readily available to the public. If a seed is not so obtainable or available, a deposit thereof may satisfy the requirements of 35 U.S.C. 112. The specification does not disclose a reproducible process to obtain the exact same seed in each occurrence and it is not apparent if such a seed is readily available to the public. If the deposit of the seed is made under the terms of the Budapest Treaty, then an affidavit or declaration by the Applicant, or a statement by an attorney of record over his or her signature and registration number, stating the seed have been deposited under the Budapest Treaty and that the seed will be irrevocably, and without restriction or condition, released to the public upon the issuance of a patent would satisfy the deposit requirement made herein. A minimum deposit of 2500 seeds is considered sufficient in the ordinary case to assure availability through the period for which a deposit must be maintained.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, Applicant may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that

(a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the enforceable life of the patent, whichever is longer;

(d) the viability of the biological material at the time of deposit will be tested (see 37 CFR 1.807); and

(e) the deposit will be replaced if it should ever become unviable.

Since Applicant intends to deposit the seeds at the ATCC, providing the ATCC Accession No. and a declaration to indicate compliance with all requirements set forth in 37 CFR 1.801-1.809 would be sufficient to overcome this rejection. Compliance with this requirement may be held in abeyance until the application is otherwise in condition for an allowance.

Claim Rejections - 35 USC § 112, 1st paragraph, written description

8. Claims 18 and 23-24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claimed invention lacks written description under current written description guidelines. The claims are drawn to hybrid corn plants having undisclosed identifying characteristics whereby only one parent in the first cross is known, and none of the characteristics of the second parent are known. The claims are also drawn to a method of producing an inbred corn plant derived from corn variety I000091 by crossing a progeny plant for 3-11 generations, each time with an unknown parent.

Applicant should note that no identifying characteristics are set forth for the claimed hybrid F1 progeny. Further, no identifying characteristics are set forth for the second parent. Applicant does not indicate that the claimed F1 progeny would have all of physiological and morphological characteristics of the I000091 parent. While Table 2 sets forth the traits for a hybrid, the claims are not limited to this particular hybrid by its hybrid designation or by any particular traits. Different hybrids would have different traits, depending on what the genetic makeup of the second parent is. Other hybrids may have traits which are vastly different from the traits in these tables. Thus, F1 progeny plants which are not claimed by any identifying characteristics are not considered to be possessed by Applicant, and one skilled in the art would not be able to predictably determine whether or not a particular corn plant is encompassed by the claims.

A method of producing an inbred corn plant derived from I000091 by outcrossing with a non-I000091 parent for 3-11 generations lacks adequate written description because only one parent from the first cross is known, and none of the parents of any of the subsequent crosses is known. No selection for any particular morphological or physiological trait is indicated for the progeny plants obtained at any generation level. If the claimed F1 plant itself cannot be identified by characteristics clearly disclosed in the specification, then it is not even possible to determine whether a plant of unknown parentage is or is not covered by the claim. There is insufficient relevant identifying characteristics to allow one skilled in the art to predictably determine the genomic structure or phenotypic characteristics of the plant obtained at each level of crossing or

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at each generation, absent further guidance. Over multiple generations, such as 3-11 generations as claimed here, the identifying characteristics for each generation become highly unpredictable, especially in view of the fact that none of the identifying characteristics of the progeny plants are disclosed in the specification or set forth in the claims. Additionally, neither the starting materials nor the end product is adequately described. Applicant should note that methods which generate F1 are adequately described because the F0 parent is adequately described, and crossing an F0 parent with another parent to select for particular traits or characteristics in the F1 progeny plants is routine in the art. However, in methods to generate F2 and subsequent generations, no traits or characteristics are disclosed for the F1 parent, as indicated above. The disclosure of F1 traits is essential to the claimed invention since the F1 parent is required to generate F2 progeny plants. Thus, these methods would involve crossing two parents having unknown characteristics to generate F2 progeny plants having unknown characteristics. Thus, absent any disclosure of what the starting materials are for each of the crosses, one skilled in the art cannot predictably determine what plants should be used for each cross and what identifiable plants are obtained upon completion of the claimed method.

Accordingly, there is a lack of adequate description for the claimed hybrid progeny plants and method of using the deposited plant material in multiple crosses to introduce undisclosed genes or traits. In view of the level of knowledge and skill in the art, one skilled in the art would not recognize from the disclosure that Applicant was in possession of the claimed invention at the time of filing. Thus, for the reasons set forth

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above, the claimed invention lacks adequate written description under current written description guidelines (see Written Description Requirement published in Federal Register/ Vol. 66, No. 4/ Friday, January 5, 2001/ Notices; p. 1099-1111).

Claim Rejections - 35 USC § 112, enablement

9. Claims 18-22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods which involve one outcrossing to introduce a particular trait and 3-10 backcrossings to the deposited parent such that the resulting progeny plant contains the desired trait and all the physiological and morphological characteristics of variety I91866, does not reasonably provide enablement for methods which involve multiple outcrossings or methods which do not select for an identifiable trait. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claim 18 is directed to a method of producing an inbred corn plant. However, the method steps encompass outcrossings with genetically distinct parents which would not result in an inbred corn plant but rather a hybrid corn plant. Since Applicant provided no working examples of any inbred plants produced by the method of claim 18, and the art does not recognize that 3-11 generations of outcrossings would result in an inbred plant, Applicant has not enabled the claimed invention as commensurate in scope with the claims.

With regard to claims 19-22, these methods are not enabled because neither Applicant's disclosure nor the state of the prior art recognizes that two backcrosses is

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sufficient to produce a converted corn plant containing a new trait not present in the I000091 variety. Murray et al. (Proceedings of the 43rd Annual Corn and Sorghum Research Conference, Vol. 43, pp.72-87, 1988 (U)) teaches the failure to obtain any variety-specific molecular markers in six different inbreds (p79); and linkage drag in corn results in 10% rather than 1% of the donor parent genome following ten backcrosses. Thus, it is unpredictable that the method set forth in these claims would result in a corn plant having all of the physiological and morphological traits of I000091 and one additional trait following two backcrosses. Applicant provided no guidance as to how the problems set forth by Murray could be overcome. The claims are not limited to any particular trait that can be reliably and predictably introduced into the I000091 variety without additional undesirable traits from the donor parent. Applicant provided no working example of a conversion corn plant having a new trait by the claimed method. Accordingly, Applicant has not enabled the claimed invention as commensurate in scope with the claims.

Accordingly, Applicant has not enabled the claimed invention as commensurate in scope with the claims.

Claim Rejections - 35 USC § 102 and 35 USC § 103

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 23-24 are rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lubich (US Pat. No. 6437224 (A)). The prior art teaches a corn plant which shares some of the traits of I000091, including leaf, anther, glume, silk, and fresh and dry husk color. While the corn variety of the prior art has a different variety designation from the corn variety of the instant application, there are insufficient identifying characteristics set forth in the claims to distinguish the claimed plants from those of the prior art. At the F1 progeny level, no identifying characteristics are recited to distinguish Applicant's F1 plants from that of the prior art. The claims do not specifically recite a plant whereby all of the physiological and morphological characteristics of the I000091 parent are retained. The method used to produce the claimed plants involves crossing I000091 with an unknown parent, and not all of the distinguishing characteristics of the I000091 parent are necessarily retained. None of the identifying features which distinguish Applicant's plants from those of the prior art are claimed. The method of producing the plant, namely using I000091 as the one parent, would not confer a unique property to the resultant corn which would distinguish it from the prior art plant. Accordingly, the claimed invention is anticipated by, or in the alternative, is obvious in view of the prior art. See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim

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may be properly rejected over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products. Since the Patent Office does not have the facilities to examine and compare the plant of Applicant's with that of the prior art, the burden of proof is upon the Applicant to show an unobvious distinction between the claimed plant and the plant of the prior art. See *In re Best*, 562F.2d 1252, 195 USPQ 430 (CCPA 1977). Accordingly, the claimed invention is anticipated by or is rendered obvious in view of the prior art.

Conclusion

13. No claim is allowed.

14. Any inquiry concerning this communications from the Examiner should be directed to Phuong Bui, whose telephone number 571-272-0793.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Jones, can be reached at 571-272-0745.

The fax phone number for the organization where this application or proceeding is assigned, for sending official correspondence, is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

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Phuong T. Bui

Primary Examiner

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